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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,970	01/03/2001	Hideaki Nomura	081356/0156	8299

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	8

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/720,970	Applicant(s) NOMURA ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-9 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-9 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt for Continued Prosecution Application, Amendment A, and Rule 132 Declaration is acknowledged. Claims 1-2, 6-9, and 13-20 are pending in this application. Claims 3-5 and 10-12 stand cancelled.

Response to Amendment

The Declaration under 37 CFR 1.132 filed June 24, 2003 is insufficient to overcome the rejection of claims based on WO 90/09870.

The examiner points out that applicant claims on page 2 of the Declaration that an insert including data is provided; however an insert was not provided to analyze the claimed data.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on Amendment D.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 9, 13, 15, and 19-20 are rejected under 35 U.S.C. 102(e) as b ing anticipated by Chen et al (5,889,051).

Chen et al disclose a solid drug dispersion of prostaglandin and instant polymer (Eudragit RS) in instant amounts. Conventional excipients are included. See examples and column 4, line 18).

*Note claim 9 and15 contains "intended use" language that does not hold patentable weight unless the recitation imparts a structural limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7, 9, 13-17, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cumming et al (6,153,220).

Cumming et al teach a taste-masked formulation containing a cationic copolymer (Eudragit E 100) and a drug in powder form. See Abstract and examples. Cumming teaches drugs such as peptides, proteins, and hormones in the composition. See

column 3, lines 9-10. Several ratios are taught such as 1:1, 1:2, 1:10, etc. See Table 1. The composition may include conventional excipients (adjuvant). See examples.

Cummings does not exemplify the instant drugs.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Cumming and utilize the instant drugs in the composition. One would be motivated to do so since Cumming teaches the suitability of proteins, peptides, and hormones as the active agent. Therefore, one would be motivated to utilize a particular drug depending on the symptom to be treated.

Claims 1-2, 6-9, 13-17, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al (5,958,458).

Norling et al disclose a particulate formulation in the form of coated cores. The cores comprise active agents such as hormones, peptides, calcitonin, insulin, colony stimulating factors, theophylline (hapten), etc. See column 7 and 8. The cores additionally contain a coating such as a film coating based on one or more materials such as HPMC, Eudragit E or modified release coat such as Eudragit RL or RS, or a combination of coatings in instant amount. See column 9, line 43 to column 10, line 20 and example 10. Excipients are taught, especially binding agents such as HPMC. See column 13, lines 40-65. Inert carriers are taught on column 5, lines 9-15. Nasal formulations are taught on column 14, lines 44-65.

Norling does not exemplify instant drugs.

It is deemed obvious of one of ordinary skill in the art at the time the invention was made to look to the guidance of Norling et al and utilize instant drug. One would be

motivated to do so since Norling teaches insulin, calcitonin, GCSF, and peptides are suitable as active agents in the particulate formulation. Therefore, one would be motivated to utilize a particular drug depending on the symptom to be treated.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al (5,958,458) JP 406065090.

Norling et al disclose a particulate formulation in the form of coated cores. The cores comprise active agents such as hormones, peptides, calcitonin, insulin, colony stimulating factors, theophylline (hapten), etc. See column 7 and 8. The cores additionally contain a coating such as a film coating based on one or more materials such as HPMC, Eudragit E or modified release coat such as Eudragit RL or RS, or a combination of coatings in instant amount. See column 9, line 43 to column 10, line 20 and example 10. Excipients are taught, especially binding agents such as HPMC. See column 13, lines 40-65. Inert carriers are taught on column 5, lines 9-15. Nasal formulations are taught on column 14, lines 44-65.

Norling et al do not specify G-CSF.

JP teaches G-CSF in a nasal formulation for curing leucopoenia.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Norling et al and JP and utilize G-CSF. One would be motivated to do so since JP teaches that the instant active treats leucopoenia. Further, one would be motivated to do so with the expectation of similar results since Norling et al teach the suitability of CSF in the formulation. Therefore, one would be motivated to utilize G-CSF in the formulation to treat leucopoenia.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al (5,958,458) in view of Stanton et al (5,807,552).

Norling et al disclose a particulate formulation in the form of coated cores. The cores comprise active agents such as hormones, peptides, calcitonin, insulin, colony stimulating factors, theophylline (hapten), etc. See column 7 and 8. The cores additionally contain a coating such as a film coating based on one or more materials such as HPMC, Eudragit E or modified release coat such as Eudragit RL or RS, or a combination of coatings in instant amount. See column 9, line 43 to column 10, line 20 and example 10. Excipients are taught, especially binding agents such as HPMC. See column 13, lines 40-65. Inert carriers are taught on column 5, lines 9-15. Nasal formulations are taught on column 14, lines 44-65.

Norling et al do not specify a protein that is conjugated to a hapten.

Stanton et al teach the use of hapten-carrier (protein) molecules for use in human and animal prophylaxis. Stanton teaches the hapten-carrier molecules illicit immune response and functions as vaccine (col. 3, lines 10-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Norling et al and Stanton et al and utilize a hapten conjugated protein. One would be motivated to do so since hapten-carrier (protein) molecules function as a vaccine as taught by Stanton et al. Therefore, one would be motivated to incorporate a specific medicine depending on the symptoms to be treated or desired affect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER